

requirement of this subpart for a specified device or a specified type of device. A written request for an exception or alternative must:

(1) Identify the device or devices that would be subject to the exception or alternative;

(2) Identify the provisions of this subpart that are the subject of the request for an exception or alternative;

(3) If requesting an exception, explain why you believe the requirements of this subpart are not technologically feasible;

(4) If requesting an alternative, describe the alternative and explain why it would provide for more accurate, precise, or rapid device identification than the requirements of this subpart or how the alternative would better ensure the safety or effectiveness of the device that would be subject to the alternative;

(5) Provide, if known, the number of labelers and the number of devices that would be affected if we grant the requested exception or alternative; and

(6) Provide other requested information that the Center Director needs to clarify the scope and effects of the requested exception or alternative.

(b) A written request for an exception or alternative must be submitted by sending it:

(1) If the device is regulated by the Center for Biologics Evaluation and Research (CBER), by email to: *cberudirequests@fda.hhs.gov* or by correspondence to: Office of Communication, Outreach and Development (HFM-40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852-1448.

(2) In all other cases, by email to: *udi@fda.hhs.gov*, or by correspondence to: UDI Regulatory Policy Support, Center for Devices and Radiological Health, Food and Drug Administration, Bldg. 66, Rm. 3303, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002.

(c) The Center Director may grant an exception or alternative, either in response to a request or on his or her own initiative, if the Center Director determines that an exception is appropriate because the requirements of this subpart are not technologically feasible, or that an alternative would provide

for more accurate, precise, or rapid device identification than the requirements of this subpart or would better ensure the safety or effectiveness of the device that would be subject to the alternative. If we grant an exception or alternative, we may include any safeguards or conditions deemed appropriate to ensure the adequate identification of the device through its distribution and use. Any labeler may make use of an exception or alternative granted under this section, provided that such use satisfies all safeguards or conditions that are part of the exception or alternative.

(d) FDA may initiate and grant an exception or alternative if we determine that the exception or alternative is in the best interest of the public health. Any such exception or alternative will remain in effect only so long as there remains a public health need for the exception or alternative.

(e) The Center Director may rescind an exception or alternative granted under this section if, after providing an opportunity for an informal hearing as defined in section 201(x) of the Federal Food, Drug, and Cosmetic Act and under part 16 of this chapter, the Center Director determines that the exception or alternative no longer satisfies the criteria described in this paragraph (e) or that any safeguard or condition required under this paragraph (e) has not been met.

[78 FR 58818, Sept. 24, 2013]

**§ 801.57 Discontinuation of legacy FDA identification numbers assigned to devices.**

(a) On the date your device must bear a unique device identifier (UDI) on its label, any National Health-Related Item Code (NHRIC) or National Drug Code (NDC) number assigned to that device is rescinded, and you may no longer provide an NHRIC or NDC number on the label of your device or on any device package.

(b) If your device is not required to bear a UDI on its label, any NHRIC or NDC number assigned to that device is rescinded as of September 24, 2018, and beginning on that date, you may no longer provide an NHRIC or NDC number of the label of your device or on any device package.

(c) A labeler who has been assigned an FDA labeler code to facilitate use of NHRIC or NDC numbers may continue to use that labeler code under a system for the issuance of UDIs, *provided that*—

(1) Such use is consistent with the framework of the issuing agency that operates that system; and

(2) No later than September 24, 2014, the labeler submits, and obtains FDA approval of, a request for continued use of the assigned labeler code. A request for continued use of an assigned labeler code must be submitted by email to: [udi@fda.hhs.gov](mailto:udi@fda.hhs.gov), or by correspondence to: UDI Regulatory Policy Support, Center for Devices and Radiological Health, Food and Drug Administration, Bldg. 66, Rm. 3303, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002.

(d) Each request for continued use of an assigned labeler code must provide—

(1) The name, mailing address, email address, and phone number of the labeler who is currently using the labeler code;

(2) The owner/operator account identification used by the labeler to submit registration and listing information using FDA's Unified Registration and Listing System (FURLS).

(3) The FDA labeler code that the labeler wants to continue using.

[78 FR 58820, Sept. 24, 2013]

## Subpart C—Labeling Requirements for Over-the-Counter Devices

### § 801.60 Principal display panel.

The term *principal display panel*, as it applies to over-the-counter devices in package form and as used in this part, means the part of a label that is most likely to be displayed, presented, shown, or examined under customary conditions of display for retail sale. The principal display panel shall be large enough to accommodate all the mandatory label information required to be placed thereon by this part with clarity and conspicuousness and without obscuring designs, vignettes, or crowding. Where packages bear alternate principal display panels, information required to be placed on the principal display panel shall be duplicated on each principal display panel. For

the purpose of obtaining uniform type size in declaring the quantity of contents for all packages of substantially the same size, the term *area of the principal display panel* means the area of the side or surface that bears the principal display panel, which area shall be:

(a) In the case of a rectangular package where one entire side properly can be considered to be the principal display panel side, the product of the height times the width of that side;

(b) In the case of a cylindrical or nearly cylindrical container, 40 percent of the product of the height of the container times the circumference; and

(c) In the case of any other shape of container, 40 percent of the total surface of the container: *Provided, however*, That where such container presents an obvious “principal display panel” such as the top of a triangular or circular package, the area shall consist of the entire top surface.

In determining the area of the principal display panel, exclude tops, bottoms, flanges at the tops and bottoms of cans, and shoulders and necks of bottles or jars. In the case of cylindrical or nearly cylindrical containers, information required by this part to appear on the principal display panel shall appear within that 40 percent of the circumference which is most likely to be displayed, presented, shown, or examined under customary conditions of display for retail sale.

### § 801.61 Statement of identity.

(a) The principal display panel of an over-the-counter device in package form shall bear as one of its principal features a statement of the identity of the commodity.

(b) Such statement of identity shall be in terms of the common name of the device followed by an accurate statement of the principal intended action(s) of the device. Such statement shall be placed in direct conjunction with the most prominent display of the name and shall employ terms descriptive of the principal intended action(s). The indications for use shall be included in the directions for use of the device, as required by section 502(f)(1) of the act and by the regulations in this part.